FDA has based these estimates on conversations with industry and trade association representatives, and from internal review of the documents listed in Tables 1 and 2 of this document. Based on the trend in the past 3 years, an estimated 5,000 submissions are expected each year. FDA's administrative and technical staff, who are familiar with the requirements for submission of premarket notifications, estimate that an average of 80 hours are required to prepare a submission (exclusive of preparing clinical data, research, etc.). FDA, therefore, estimates that a total of 400,000 hours of effort is required for the 5,000 submissions. It is also estimated that the respondents will receive requests for an average of 20,000 documents. At an estimated one-half hour to process these documents, an additional 10,000 recordkeeping hours are expected for this program.

Dated: May 28, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–14917 Filed 6–4–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95N–0182]

KV Pharmaceutical Co.; Withdrawal of Approval of Two Abbreviated New Drug Applications and One Abbreviated Antibiotic Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of two abbreviated new drug applications (ANDA's) and one abbreviated antibiotic drug application (AADA) held by KV Pharmaceutical Co. (KV), 2503 South Hanley Rd., St. Louis, MO 63144. This action is being taken because the applications contain untrue statements of material fact, and the drugs covered by these applications lack substantial evidence of effectiveness.

EFFECTIVE DATE: June 5, 1998.

FOR FURTHER INFORMATION CONTACT: David T. Read, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 26, 1995 (60 FR 32982), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of the following abbreviated applications:

AADA 62–047, Erythromycin Ethylsuccinate Oral Suspension, 200 and 400 milligrams (mg);

ANDA 71–929, Disopyramide Phosphate Extended Release Capsules, 100 mg; and

ANDA 86–538, Nitroglycerin Extended Release Capsules, 2.5 mg.

The grounds for the proposed withdrawals were: (1) That the applications contained untrue statements of material fact, and (2) that based upon new information evaluated together with the evidence available when the applications were approved, there is a lack of substantial evidence that the drugs will have the effect they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling.

On July 26, 1995, KV requested a hearing. Subsequently, in a letter dated August 25, 1995, KV withdrew its request for a hearing and requested withdrawal of these applications because the products are no longer being marketed. (AADA 62–047 was inadvertently included in a previous **Federal Register** notice (61 FR 13506, March 27, 1996) that withdrew a large number of applications based on the request of the applicants.)

Based on the information presented in the June 26, 1995, notice, the Director of the Center for Drug Evaluation and Research, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) and under authority delegated to her (21 CFR 5.82), finds that the applications listed above contain untrue statements of material fact (21 U.S.C. 355(e)(5)); and that on the basis of new information before her with respect to the drugs, evaluated together with the evidence available to her when the applications were approved, there is a lack of substantial evidence that the drugs will have the effects they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in their labeling (21 U.S.C. 355(e)(3)).

Therefore, approval of the applications listed above, and all their amendments and supplements, is hereby withdrawn, effective June 5, 1998. Distribution of these products in interstate commerce without an approved application is illegal and subject to regulatory action.

Section 505(j)(7)(C) of the act requires that FDA immediately remove from its approved product list (''Approved Drug Products with Therapeutic Equivalence Evaluation'') (''the list'') any drug whose approval was withdrawn for grounds described in the first sentence of section 505(e) of the act. Such grounds apply to this withdrawal. Notice is hereby given that the drugs covered by these applications are removed from the list.

Dated: May 28, 1998.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 98–14914 Filed 6–4–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Food Advisory Committee. This meeting was announced in the **Federal Register** of May 12, 1998 (63 FR 26194). The amendment is being made to reflect a change in the *Procedure* portion of the meeting notice. The organization and time of the oral presentations have been changed. All oral presentations will be made on June 16, 1998. There are no other changes.

FOR FURTHER INFORMATION CONTACT: Lynn A. Larsen, Center for Food Safety and Applied Nutrition (HFS–5), 202–205–4727, or Catherine M. DeRoever (HFS–22), 202–205–4251, FAX 202–205–4970, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 10564.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 12, 1998 (63 FR 26194), FDA announced that oral presentations from the public during the Food Advisory Committee meeting would be scheduled in three sessions over 2 days. However, all oral presentations have been combined into one session. On page 26195, in the first column, the *Procedure* portion of this meeting notice is amended to read as follows:

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by June 5, 1998. All oral presentations are scheduled in a